

Dkt. 55099-A-PCT-US/JPW/SH

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :

Ilya Trakht

Serial No.:

09/664,485

Filed

September 18, 2000

For

DEVELOPMENT OF HUMAN MONOCLONAL ANTIBODIES AND USES

THEREOF

1185 Avenue of the Americas New York, New York 10036

August 23, 2001

Assistant Commissioner for Patents Washington, D.C. 20231

SIR:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. § 1.56, applicants would like to direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (Exhibit A). Copies of the below listed references 29-30 are attached hereto as Exhibits 1-2, respectively.

- 1. U. S. Patent No. 4,574,116, issued to Kaplan et al. March 4, 1986;
- 2. U. S. Patent No. 4,613,576, issued to Cote et al. September 23, 1986;
- U. S. Patent No. 4,618,577, issued to Handley et al. October 21, 1986;
- 4. U. S. Patent No. 4,634,664, issued to Oestberg January

Page 2

6, 1987;

- 5. U. S. Patent No. 4,634,666, isued to Engleman et al. January 6, 1987;
- 6. U. S. Patent No. 4,668,629, issued to Kaplan et al. May 26, 1987;
- 7. U. S. Patent No. 4,689,299, issued to Insel et al. August 25, 1987;
- 8. U. S. Patent No. 4,720,459, issued to Winkelhake January 19, 1988;
- 9. U. S. Patent No. 4,744,982, issued to Hunter et al. May 17, 1988;
- 10. U. S. Patent No. 4,761,377, issued to Glassy et al. August 2, 1988;
- 11. U. S. Patent No. 4,800,155, issued to Taniguchi et al. January 24, 1989;
- 12. U. S. Patent No. 4,916,072, issued to Tsuji et al. April 10, 1990;
- 13. U. S. Patent No. 4,950,595, issued to Masuho et al. August 21, 1990;
- 14. U. S. Patent No. 4,954,449, issued to Hunter et al. September 4, 1990;
- 15. U. S. Patent No. 4,997,762, issued to Hanna Jr. et al.

Page 3

March 5, 1991;

- 16. U. S. Patent No. 5,001,065 issued to Larrick et al. March 19, 1991;
- 17. U. S. Patent No. 5,003,046, issued to Neville et al. March 26, 1991;
- 18. U. S. Patent No. 5,006,470, issued to Yamaguchi et al. April 9, 1991;
- 19. U. S. Patent No. 5,093,261, issued to Hagiwara et al. March 3, 1992;
- 20. U. S. Patent No. 5,126,259, issued to Tada et al.
 June 30, 1992;
- 21. U. S. Patent No. 5,196,337, issued to Ochi et al. March 23, 1993;
- 22. U. S. Patent No. 5,215,913, issued to Posner June 1, 1993;
- 23. U. S. Patent No. 5,252,480, issued to Yokota et al. October 12, 1993;
- 24. U. S. Patent No.5,298,419, issued to Masuho et al. March 29, 1994;
- 25. U. S. Patent No. 5,426,046, issued to Kaplan et al. June 20, 1995;
- 26. U. S. Patent No. 5,459,060, issued to Cotropia October 17, 1995;

Page 4

- 27. U. S. Patent No. 5,506,132, issued to Lake et al. April 9, 1996;
- 28. U. S. Patent No. 5,576,184, issued to Better et al. November 19, 1996;
- 29. U.S. Patent No. 6,197,582, issued to Trakht on March
 6, 2001 (Exhibit 1);
- 30. PCT International Application No. PCT/US99/05828, filed March 18, 1999, International Publication No. WO99/47929, published September 23, 1999, on behalf of The Trustees of Columbia University in the City of New York (Exhibit 2);
- 31. Brodin T, Olsson L, Sjorgen H., "Cloning of human hybridoma, myeloma and lymphoma cell lines using enriched human monocytes as feeder layer"

 J.Immunol.Meth. (1983) Vol 60, 1-7;
- 32. Goldman-Leikin, R.E., Salwen, H.R., Herst, C.V., Variakojis, D., Bian, M.L., Le Beau, M.M., Selvanayagan, P., Marder, R., Anderson, R., Weitzman, S., Rosen, S.T., "Characterization of a novel myeloma line MM-I" <u>J.Lab.Clin.Med.</u> (1989) Vol 113, 335-345;
- 33. Kozbor, D., Roder, J., "Requirements for the establishment of high titered human monoclonal antibodies against tetanus toxoid using the Epstein-Barr virus technique" <u>J.Immunology</u> (1981) Vol 127, 1275-1280;
- 34. Kozbor, D., Tripputi, P., Roder, J.C., Croce, C.M., "A

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human hybrid myeloma for production of human monoclonal antibodies" <u>J.Immunology</u> (1984) Vol 133, 3001-3005;

- 35. Levy, R., Miller, R.A., "Tumor therapy with monoclonal antibodies" <u>Federation Proceedings</u> (1983) Vol **42**, 2650-2656;
- 36. Nilsson, K., Ponten, J., "Classification and biological nature of established human hematopoetic cell lines"

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- 37. Oestberg, L., Pursch, E., "Human x (Mouse x Human)
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- 38. Posner, M.R. Schlossman, S.F., Lazarus, H., "Novel approach to the construction of human "Myeloma Analogues" for the production of human monoclonal antibodies" Hybridoma (1983) Vol 2, 369-381;
- 39. Reading, C.L., "Theory and Methods for Immunization in Culture and Monoclonal Antibody Production" <u>J.Immunol.</u>

 <u>Meth.</u> (1982) Vol **53**, 261-291;
- 40. Raison, R.L., Walker, K.Z., Halnan, C.R.E., Briscoe, D, Basten, A., "Loss of Secretion in Mouse-Human Hybrids Need Not Be Due to the Loss of a Structural Gene"

 J.Exp.Medicine (1982) Vol 156, 1380-1389;
- 41. Teng, N.N.H., Lam, K.S., Riera, F.C., Kaplan, H.S., "Construction and Testing of Mouse-Human Heteromyelomas for Human Monoclonal Antibody Production"

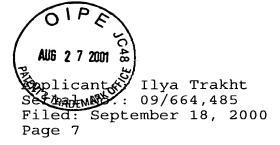
 Proc.Natl.Acad.Sci. (USA) (1983) Vol 80, 7308-7311;

Page 6

42. Weiss, M.C., Green H., "Human-Mouse Hybrid Cell Lines Containing Partial Complements of Human Chromosomes and Functioning Human Genes" Proc.Natl.Acad.Sci. (USA) (1967) Vol 58, 1104-1111.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone either of them at the number provided below.

The subject application is a continuation of PCT/US99/05828, filed March 18, 1999, which is a continuation of U.S. Serial No. 09/040,833, filed March 18, 1998. Pursuant to 37 C.F.R. §1.98(d), copies of the above-listed references 1-28 and 31-42 are not being provided since they were submitted to and considered by the United States and Trademark Office in an Information Disclosure Statement filed on November 20, 1998 in connection with the U.S. Serial No. 09/040,833 which the subject application relies on for an earlier effective filing date under 35 U.S.C. §120.



No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

John P. White Da

Reg. No. 28,678 Spencer H. Schneider

Reg. No. 45,923

John P. White

Registration No. 28,678 Spencer H. Schneider Registration No. 45,923 Attorneys for Applicant(s) Cooper & Dunham, LLP

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Exhibit A

Serial No:

Filed:

Applicants: Ilya Trakht

09/664,485

September 18, 2000

Sheet $\underline{2}$ of $\underline{6}$ Form PTO-1449 U.S. Department of Commerce U.S. Department of Commerce Atty. Docket No. Serial No. 0575/55099-A-09/664,485 PCT-US/JPW/SHS NFORMATION DISCLOSURE CITATION Applicants RADE several sheets if necessary) Ilya Trakht Filing Date Gr up September 18, 2000 U.S. PATENT DOCUMENTS Examiner **Document Number** Date Name Class Subclass Filing Date Initial if Appropriate US₄ 1/24/89 Taniguchi, et al. 6 US|4 4/10/90 Tsuji, et al. US 4 5 8/21/90 Masuho, et al. US₄ 9/4/90 Hunter, et al. US/4 3/5/91 Hanna Jr., et al. US 0 6 5 3/19/91 Larrick, et al. US 5 3 0 3/26/91 6 Neville, et al. US 5 Ю ю 6 4/9/91 Yamaguchi, et al. US 2 6 3/3/92 Hagiwara, et al. US|5 6 2 6/30/92 Tada, et al. FOREIGN PATENT DOCUMENTS **Document Number** Date Country Class **Subclass Translation** Yes No OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) **EXAMINER** DATE CONSIDERED EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to applicant.

Sheet 3 of 6 Form PTO-14**4**9 4\S. Department of Commerce Atty. Docket No. Serial No. AUS 2 7 2001 Patent and Trademark Office 0575/55099-A-09/664,485 PCT-US/JPW/SHS RMATION DISCLOSURE CITATION Applicants Ilya Trakht (Plot weral sheets if necessary) Filing Date Group September 18, 2000 **U.S. PATENT DOCUMENTS** Examiner **Document Number** Date Name Class Subclass Filing Date Initial if Appropriate US 6 3/23/93 Ochi, et al. US 6/1/93 Posner; US 2 2 8 10/12/93 Yokota, et al. 8 US 3/29/94 Masuho, et al. US 0 6/20/95 Kaplan, et al. US 9 10 6 10/17/95 Cotropia US 6 4/9/96 Lake. Et al. US 11/19/96 Better, et al. 9 US 6 3/6/01 Trakht (Exhibit 1) FOREIGN PATENT DOCUMENTS **Document Number Date** Country Class **Subclass Translation** Yes No OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Brodin T, Olsson L, Sjorgen H., "Cloning of human hybridoma, myeloma and lymphoma cell lines using enriched human monocytes as feeder layer" J.Immunol.Meth. (1983) Vol 60, 1-7;

using enriched human monocytes as feeder layer" J.Immunol.Meth. (1983) Vol 60, 1-7;
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Kozbor, D., Roder, J., "Requirements for the establishment of high titered human monoclonal antibodies against tetanus toxoid using the Epstein-Barr virus technique" <u>J.Immunology</u>

(1981) Vol 127, 1275-1280;

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Sheet 6 of 6 Form PTO-1/449 (1).S. Department of Commerce Atty. Docket No. Serial No. All 2 7 2001 Patent and Trademark Office 0575/55099-A-PCT-09/664,485 US/JPW/SHS **DISCLOSURE CITATION** Applicants (Use several sheets if necessary) Ilya Trakht Filing Date Group September 18, 2000 **U.S. PATENT DOCUMENTS** Examiner **Document Number** Date Name Class Subclass Filing Date Initial if Appropriate FOREIGN PATENT DOCUMENTS **Document Number** Date Country Class **Subclass Translation** Yes No OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Weiss, M.C., Green H., "Human-Mouse Hybrid Cell Lines Containing Partial Complements of Human Chromosomes and Functioning Human Genes" Proc. Natl. Acad. Sci. (USA) (1967) Vol 58, 1104-1111. EXAMINER DATE CONSIDERED EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in

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